Message Text

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TAGS: TBIO, JA
SUBJECT: SMON (SUBACUTE MYELO-OPTICO NEUROPATHY) VERDICT

REF: 77 TOKYO 12626

1. FOR FIRST TIME IN HISTORY OF SMON DAMAGE SUIT TRIALS IN JAPAN, ONE OF THE 23 DISTRICT COURTS HANDLING THE CASE DELIVERED VERDICT ON MARCH 1. VERDICT BY KANAZAWA DISTRICT COURT ORDERED THE STATE (CENTRAL GOVT) AND THREE DRUG FIRMS INVOLVED TO PAY YEN 249,560,000 (DOLS 1,040,000) TO A TOTAL OF 16 PLAINTIFFS.

2. GROUNDS ON WHICH VERDICT WAS HANDED DOWN ARE AS FOLLOWS: (1) MAJORITY OF PATIENTS DIAGNOSED AS SMON HAVE BEEN AFFECTED BY NEUROLOGICAL DISTURBANCES AS RESULT OF ADMINISTRATION OF QUINOFORM PLUS SOME OTHER UNIDENTIFIED FACTOR WHICH CANNOT BE DISREGARDED--SUCH AS VIRUS; (2) THE MINISTER OF HEALTH AND WELFARE, WHO IS OBLIGATED BY LAW TO CONFIRM SAFETY OF MEDICAL AND PHARMACEUTICAL PRODUCTS, LICENSED QUINOFORM DESPITE THE FACT THAT ITS TOXICITY WAS FORESEEABLE; (3) THE
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THREE FIRMS WERE ALLEGEDLY NEGLIGENT IN DISCHARGING THEIR OBLIGATION TO INSURE SAFETY OF PRODUCTS THEY MANUFACTURE, IMPORT AND SELL AND THEIR ACT IN SELLING QUINOFORM WAS ILLEGAL; AND (4) ALL THE PLAINTIFFS IN THIS CASE CAN BE REGARDED AS SUFFERING FORM SIDE-EFFECTS OF QUINOFORM IN LIGHT OF AVAILABLE DATA.

3. VERDICT OF MARCH 1 CAN BE CONSIDERED AS SETTING PRECEDENT FOR SCORES OF OTHER SMON TRIALS INVOLVING A TOTAL OF 4,071 PLAINTIFFS. THIS IS FIRST TIME THAT CENTRAL GOVERNMENT AND PHARMACEUTICAL COMPANIES HAVE BEEN CALLED UPON IN COURT TO EXERCISE UTMOST CARE IN MANUFACTURING, LICENSING AND MONITORING NEW DRUGS.

4. DESPITE VICTORY THEY WON, THE PLAINTIFFS ARE NOT SATISFIED WITH THE VERDICT BECAUSE AMOUNT OF COMPENSATION PRESCRIBED IN VERDICT WAS LESS THAN HALF THE AMOUNT THEY HAD DEMANDED, AND ALSO BECAUSE THE COURT DID NOT RULE OUT THE VIRUS THEORY. ACCORDING TO PRESIDING JUDGE INOUE OF THE DISTRICT COURT, REASON FOR SETTING AMOUNT OF COMPENSATION AT LOWER LEVEL THAN HAD BEEN DEMANDED BY THE PLAINTIFFS IS THAT EXTENT OF NEGLIGENCE AND MORAL CENSURABILITY ON PART OF THE STATE AND DRUG FIRMS COULD NOT BE CONSIDERED EXCEPTIONALLY HIGH, AND THAT CONSIDERATION WAS GIVEN TO FACT THAT THE STATE HAS INVESTED HEAVILY IN DAMAGE PREVENTION AND PATIENT RELIEF SINCE OCCURRENCE OF DAMAGE.

5. ACCORDING TO ASAHI SHIMBUN, THE DISTRICT COURT VERDICT HAS SHED LIGHT ON QTE SLIPSHOD ADMINISTRATION OF PHARMACEUTICAL AFFAIRS BY THE CENTRAL GOVERNMENT AND DRAWBACKS OF EXISTING PHARMACEUTICAL AFFAIRS LAW UNCLASSIFIED

UNQTE. AS RESULT OF COURT DECISION, THE PAPER SAID, GOVERNMENT WILL BE FORCED TO REVISE THE LAW TO EMPHASIZE SAFETY OF DRUGS AND TO ENACT NEW LEGISLATION DESIGNED TO EXTEND RELIEF TO PEOPLE SUFFERING FROM SIDE-EFFECTS OF DRUGS. ACTUALLY, MHW HAD BEEN WAITING FOR THIS FIRST COURT DECISION TO SEE HOW GOVERNMENT RESPONSIBILITIES WILL BE DEFINED IN CASES LIKE SMON. SEVERAL POINTS ARE ALREADY IN THE MIND OF MHW OFFICIALS IN REVISINGGTHE LAW: (1) DRUG MANUFACTURERS WILL BE REQUIRED TO SUBMIT GREATER AMOUNT OF EXPERIMENTAL DATA IN APPLYING FOR LICENSE FOR NEW DRUG; (2) DRUG MANUFACTURERS ARE REQUIRED TO SUBMIT INFORMATION ON SIDE-EFFECTS OF DRUGS AND ALL NEW DRUGS WILL BE SUBJECT TO MONITORING; (3) NEW DRUGS WILL BE REEVALUATED FIVE YEARS AFTER ISSUANCE OF LICENSE; (4) NEW PROVISIONS WILL BE MADE FOR BANNING SALE OF DRUGS IN QUESTION AND FOR THEIR RECOVERY AND DISPOSAL; (5) CANCELLING LICENSE IN EVENT DAMAGE TO HUMAN HEALTH FROM SIDE-EFFECTS HAS BEEN ESTABLISHED; AND (6) INSTITUTIONALIZING GMP. IT MAY APPEAR STRANGE THAT THESE REQUIREMENTS, ALL ESSENTIAL TO PREVENTION OF DAMAGE BY DRUGS, HAVE NOT BEEN EXPLICITY PROVIDED IN EXISTING LAW; IN ACTUALITY THESE REQUIREMENTS HAVE BEEN

BROUGHT TO ATTENTION OF DRUG MANUFACTURERS THROUGH
ADMINISTRATIVE GUIDANCE, A TRADITIONAL PROCEDURE
ADOPTED BY ALL GOJ AGENCIES IN DEALING WITH PRIVATE
SECTOR WHICH HAS NO LEGAL BINDING POWER.
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